

### Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to incorporate the subject matter of claim 4, and amended claim 1 is further based on the disclosure at page 13, lines 9-23 of the specification.

As a result of the amendments to claim 1, claims 4 and 6 have been cancelled.

Claims 5 and 8 have been to depend from claim 1.

Claim 7 has been amended to make minor changes which are self-explanatory.

Claim 9, which has been withdrawn from consideration as being directed to non-elected subject matter, has been cancelled. Applicants emphasize that this is without prejudice to their rights under 35 U.S.C. §121 to file a divisional application for the subject matter of claim 9.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1-6 and 8 under 35 U.S.C. §102(b) as being anticipated by DeProspero (US '869) is respectfully traversed.

As a result of the above amendment, the process of the present invention (claim 1) is an industrially feasible process for producing an aliphatic polyester with a reduced residual monomer content of below 0.2 wt.%.

As described at paragraph [0008] of the specification, the present invention aims at providing a process for producing an aliphatic polyester with a minimized content, more specifically a securely reduced content of less than 0.2 wt.%, of residual monomer, since such a residual monomer causes a lowering in melt-extrudability and stretchability of the product aliphatic polyester, and also degradation or fluctuation of properties of the product obtained therefrom (e.g., cutting of filaments or local lowering of properties of films) as described in paragraph [0006]. This object is achieved by a combination of a step of residual monomer reduction down to about 0.3 - 0.8 wt.% by solid-phase polymerization of cyclic ester, and a subsequent step of residual monomer reduction down to below 0.2 wt.% by contact of the aliphatic polyester particles with a flowing heated dry gas under normal pressure (claim 1).

The process of the present invention is first characterized by contact of a particulate aliphatic polyester with a flowing heated dry gas under normal pressure as a step for finally

reducing the residual monomer content down to below 0.2 wt.%. The step of contact with a flowing heated dry gas under normal pressure is not as effective as application of a reduced pressure as far as the residual monomer reduction effect is concerned, but is safe and suited for mass production (page 13, lines 17-19). In order to compensate for such a relatively low residual monomer reduction capacity of the final step, the present invention relies on the solid-phase polymerization as a preceding step for reducing the residual monomer content after the polymerization to the minimum, i.e., down to about 0.3 - 0.8 wt.%, by utilizing the advantage of polymerization/depolymerization equilibrium.

Referring to Table 1 on page 25 of the specification, Comparative Example 1 (polymerization temperature: 170 °C) represents solid-phase polymerization, and Comparative Example 4 (polymerization temperature: 230 °C) represents non-solid-phase polymerization (or melt polymerization). Comparing these Examples, it is clear that solid-phase polymerization (residual monomer (glycolide): 0.35 wt.% in Comparative Example 1) is more advantageous than non-solid-phase polymerization (residual monomer: 1.0 wt.% in Comparative Example 4). This is because the polymerization/depolymerization equilibrium is in favor of solid-phase polymerization using a lower polymerization temperature as discussed in paragraph [0010] of the specification.

However, the residual monomer content below 0.2 wt.% aimed at by the present invention cannot be achieved by only the solid-phase polymerization. Accordingly, in the present invention, the aliphatic polyester resulting from solid-phase polymerization is subjected to contact with a flowing heated dry gas under normal pressure to realize a residual monomer content below 0.2 wt.% (0.04 - 0.18 wt.% in Examples 2, 4 and 6-12).

Such a process for producing an aliphatic polyester by combining a solid-phase polymerization step in consideration of polymerization/depolymerization equilibrium, and a subsequent step of removal of residual monomer by contact with a flowing heated dry gas under normal pressure for accomplishing a residual monomer content below 0.2 wt.%, has not been known before the present invention.

DeProspero, which is cited and discussed on pages 2-4 of the present specification, discloses a process for producing polyglycolic acid in particle form suitable for production of filaments usable as surgical sutures by contact with a flowing dry gas under a reduced pressure (claim 1). The process has succeeded in providing a residual monomer content below 0.2 wt.%

(column 3, lines 34-40). The process simply relies on the application of severe gas-phase monomer removal conditions (i.e., contact with a heated dry gas **under a reduced pressure** as described at column 3, lines 34-44 and claim 1) to impure solid polyglycolic acid containing as much as 8 wt.% of residual monomer (column 1, line 56 and column 5, lines 28-29). DeProspero fails to disclose or suggest a solid-phase polymerization step for providing a residual monomer content of about 0.3-0.8 wt.% as a suitable step preceding the severe gas-phase monomer removal step. The reference process may be suitable for producing polyglycolic acid on a small scale satisfying the need for producing surgical sutures, but is not feasible for an industrial- scale production of polyglycolic acid suitable as materials for production of general purpose products, since it involves a substantial loss (8 wt.% - 0.2 wt.%) of polyglycolic acid product, and application of a reduced pressure which is risky and not suitable for mass production, as alluded to above. Thus, DeProspero fails to teach or suggest the process of the present invention characterized by a combination of a solid-phase polymerization for providing a residual monomer content of about 0.3 - 0.8 wt.% and a subsequent step of removal of residual monomer by contact with a flowing heated dry gas under normal pressure for providing a residual monomer content below 0.2 wt.%.

The rejection of claim 7 under 35 U.S.C. §103(a) as being unpatentable over DeProspero in view of Yamane et al. (US '431) is respectfully traversed.

The comments set forth above concerning DeProspero are equally applicable to this rejection, since claim 7 is dependent on claim 1, which is patentable over DeProspero for the reasons already discussed.

Yamane et al. do not remedy the deficiencies of DeProspero, as discussed above. Moreover, Yamane et al. teach the effectiveness of a thermal stabilizer for improving the stability of polyglycolic acid, but do not teach that the addition of such a thermal stabilizer is effective as a means for reducing the residual cyclic ester by contact of the polyglycolic acid with a flowing heated dry gas under normal pressure.

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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